EXHIBIT P

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SILVERGATE PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AMNEAL PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Silvergate Pharmaceuticals, Inc. ("Silvergate"), by and through its attorneys, for its Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 9,669,008 ("the '008 patent"), 9,808,442 ("the '442 patent"), 10,039,745 ("the '745 patent"), and 10,154,987 ("the '987 patent") (collectively, the "Patents-in-Suit") under the patent laws of the United States, Title 35, United States Code, arising out of the submission by Amneal of Abbreviated New Drug Application ("ANDA") No. 212894 to the U.S. Food and Drug Administration ("FDA") seeking approval of a generic version of Silvergate's oral solution formulation that is the subject of New Drug Application ("NDA") No. 208686, hereinafter referred to as Silvergate's "Epaned® product." Silvergate seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and other applicable laws for Amneal's infringement of the Patents-in-Suit.

THE PARTIES

2. Silvergate is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6251 Greenwood Plaza Blvd., Suite 101, Greenwood Village, CO 80111.

3. On information and belief, Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

4. On information and belief, Amneal is in the business of, among other things, developing, manufacturing, and selling generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100, *et seq*. and from Amneal's submission of ANDA No. 212894 ("Amneal's ANDA").

6. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Amneal because of, among other things, on information and belief, Amneal's persistent and continuous contacts with Delaware. Amneal has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Amneal is a limited liability company formed under the laws of the State Delaware and is registered to do business in Delaware. On information and belief, Amneal regularly and continuously transacts business in Delaware, including by selling pharmaceutical products in Delaware. On information

and belief, Amneal derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

8. On information and belief, Amneal derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in Delaware.

9. On information and belief, this judicial district is a likely destination of the product that is the subject of Amneal's ANDA.

10. Venue is proper in this Court under 28 U.S.C. § 1400(b).

SILVERGATE'S EPANED® PRODUCT

11. Silvergate's Epaned® product is the only FDA approved and labeled ace inhibitor treatment that is a ready-to-use oral solution for hypertension in children. Epaned® is also indicated to treat hypertension in adults, heart failure, and asymptomatic left ventricular dysfunction.

12. Silvergate holds approved NDA No. 208686 for its Epaned® product.

PATENTS-IN-SUIT

13. The '008 patent, entitled "Enalapril Formulations," issued to Gerold Mosher and David Miles on June 6, 2017. A true and correct copy of the '008 patent is attached to this Complaint as Exhibit A.

14. The '008 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the '008 patent.

15. Silvergate's Epaned® product is covered by at least one claim of the '008 patent.

16. Pursuant to 21 U.S.C. § 355, the '008 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") in connection with Silvergate's Epaned® product.

17. The ’442 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on November 7, 2017. A true and correct copy of the ’442 patent is attached to this Complaint as Exhibit B.

18. The ’442 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’442 patent.

19. The use of Silvergate’s Epaned® product is covered by at least one claim of the ’442 patent.

20. The approved indications for Silvergate’s Epaned® product are covered by at least one claim of the ’442 patent.

21. Pursuant to 21 U.S.C. § 355, the ’442 patent is listed in the Orange Book in connection with Silvergate’s Epaned® product.

22. The ’745 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on August 7, 2018. A true and correct copy of the ’745 patent is attached to this Complaint as Exhibit C.

23. The ’745 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’745 patent.

24. Silvergate’s Epaned® product is covered by at least one claim of the ’745 patent.

25. Pursuant to 21 U.S.C. § 355, the ’745 patent is listed in the Orange Book in connection with Silvergate’s Epaned® product.

26. The ’987 patent, entitled “Enalapril Formulations,” issued to Gerold Mosher and David Miles on December 18, 2018. A true and correct copy of the ’987 patent is attached to this Complaint as Exhibit D.

27. The ’987 patent was duly and legally issued to Silvergate as the assignee and Silvergate owns all rights, title, and interest in the ’987 patent.

28. The use of Silvergate’s Epaned® product is covered by at least one claim of the ’987 patent.

29. The approved indications for Silvergate’s Epaned® product are covered by at least one claim of the ’987 patent.

30. Pursuant to 21 U.S.C. § 355, the ’987 patent is listed in the Orange Book in connection with Silvergate’s Epaned® product.

INFRINGEMENT BY AMNEAL

31. By letter dated February 27, 2019 (“Notice Letter”), Amneal notified Silvergate that it had submitted ANDA No. 212894 to FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of Silvergate’s Epaned® product (“the Amneal ANDA Product”) before the expiration of the Patents-in-Suit.

32. On information and belief, Amneal intends to engage in commercial manufacture, use, and sale of the Amneal ANDA Product promptly upon receiving FDA approval to do so.

33. By submitting ANDA No. 212894, Amneal has represented to FDA that the Amneal ANDA Product has the same active ingredients as Silvergate’s Epaned® product, has the same route of administration, dosage form, use, and strength as Silvergate’s Epaned® product, and is bioequivalent to Silvergate’s Epaned® product.

34. This action is being filed within forty-five (45) days of Silvergate’s receipt of the Notice Letter.

CLAIMS FOR RELIEF

Count I—Infringement of the '008 patent

35. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

36. Amneal submitted ANDA No. 212894 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States before the expiration of the '008 patent. By submitting the ANDA, Amneal has committed an act of infringement of one or more claims of the '008 patent under 35 U.S.C. § 271(e).

37. If Amneal's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will constitute acts of infringement of the '008 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

38. On information and belief, Amneal had actual and constructive knowledge of the '008 patent prior to submitting ANDA No. 212894 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '008 patent. In addition, on information and belief, Amneal had specific intent to infringe the '008 patent when it filed ANDA No. 212894. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than as the pharmaceutical claimed in the '008 patent.

39. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count II—Infringement of the '442 patent

40. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

41. Amneal submitted ANDA No. 212894 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States before the expiration of the '442 patent. By submitting the ANDA, Amneal has committed an act of infringement of one or more claims of the '442 patent under 35 U.S.C. § 271(e).

42. If Amneal's ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will constitute acts of infringement of the '442 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

43. On information and belief, Amneal had actual and constructive knowledge of the '442 patent prior to submitting ANDA No. 212894 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '442 patent. In addition, on information and belief, Amneal had specific intent to infringe the '442 patent when it filed ANDA No. 212894. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than the methods claimed in the '442 patent.

44. The commercial use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count III—Infringement of the '745 patent

45. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

46. Amneal submitted ANDA No. 212894 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States before the expiration of the '745 patent. By submitting the ANDA, Amneal has committed an act of infringement of one or more claims of the '745 patent under 35 U.S.C. § 271(e).

47. If Amneal's ANDA is approved by FDA, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will constitute acts of infringement of the '745 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

48. On information and belief, Amneal had actual and constructive knowledge of the '745 patent prior to submitting ANDA No. 212894 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '745 patent. In addition, on information and belief, Amneal had specific intent to infringe the '745 patent when it filed ANDA No. 212894. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than as the pharmaceutical claimed in the '745 patent.

49. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Count IV—Infringement of the '987 patent

50. Silvergate incorporates each of the preceding paragraphs as if fully set forth herein.

51. Amneal submitted ANDA No. 212894 to FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product throughout the United States before the expiration of the '987 patent. By submitting the ANDA, Amneal has committed an act of infringement of one or more claims of the '987 patent under 35 U.S.C. § 271(e).

52. If Amneal's ANDA is approved by FDA, the commercial use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will constitute acts of infringement of the '987 patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

53. On information and belief, Amneal had actual and constructive knowledge of the '987 patent prior to submitting ANDA No. 212894 and was aware that submission of this ANDA to FDA constituted an act of infringement of the '987 patent. In addition, on information and belief, Amneal had specific intent to infringe the '987 patent when it filed ANDA No. 212894. Moreover, there are no substantial non-infringing uses for the Amneal ANDA Product other than the methods claimed in the '987 patent.

54. The commercial use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of Silvergate's patent rights will cause substantial and irreparable harm to Silvergate for which damages are inadequate.

Prayer for Relief

Silvergate respectfully requests the following relief:

a) A judgment that Amneal has infringed the ’008 patent, the ’442 patent, the ’745 patent, and the ’987 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212894 under Section 505(j) of the FDCA, and that Amneal’s making, using, offering to sell, or selling in the United States or importing into the United States of the Amneal ANDA Product will infringe one or more claims of the ’008 patent, the ’442 patent, the’745 patent, and the’987 patent;

b) A finding that the ’008 patent, the ’442 patent, the ’745 patent, and the ’987 patent are valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 212894 shall be a date which is not earlier than the latest expiration date of the ’008 patent, the ’442 patent, the ’745 patent, and the ’987 patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Amneal, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture use, offer to sell, or importation into the United States, of any drug product the use of which is covered by the ’008 patent, the ’442 patent, the ’745 patent, and the ’987 patent, including the Amneal ANDA Product;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Silvergate be awarded reasonable attorneys’ fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

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